SUNDAY, MAY 23, 2004

TESTIMONY BEFORE NIH PUBLIC HEARING ON

MARCH-IN RIGHTS UNDER THE BAYH-DOLE ACT

Washington, D.C., May 25, 2004

Statement of Jerome H. Reichman
Bunyan S. Womble Professor of Law
Duke University School of Law
Durham, North Carolina 27708

Jerome H. Reichman
Bunyan S. Womble Professor of Law
DUKE UNIVERSITY
School of Law
Box 90360
Durham, NC 27708-0364
Telephone: 919-613-7286
Telefax: 919-668-0995
Reichman@law.duke.edu

Statement of Jerome H. Reichman

I am Jerome H. Reichman, the Bunyan S. Womble Professor of Law at Duke University School of Law, in Durham, North Carolina. I have recently written a three-part, book length study, entitled *Nonvoluntary Licensing of Patented Inventions: The Law and Practice of Canada and the United States*, for the United Nations Conference on Trade and Development (UNCTAD), in Geneva, Switzerland.[1] Because of my expertise on compulsory licensing in domestic and foreign law, I have been asked to comment on the meaning of certain provisions in the Bayh-Dole Act that require patented products resulting from federally funded research to be made "available to the public on reasonable terms."[2]

In general, the compulsory licenses that States may impose on foreigners' patented inventions under current international law—that is, under the Paris Convention for the Protection of Industrial Property of 1883 and the WTO Agreement on Trade-Related Aspects of Intellectual Property of 1994 (TRIPS Agreement)[3]—fall into five categories. These are:

1. Antitrust violations
2. Abuses of the patentee's exclusive rights
3. Compulsory licenses to promote some overriding public interest
4. Government use of patents
5. Dependent patents, i.e., licenses that allow an improver to use a dominant patent so as to avoid blocking technological progress.[4]

Most developed countries have enacted statutes enabling government authorities to authorize third-party private uses of patented inventions when breaking the inventor's legal monopoly is deemed necessary to correct an abuse of the patentee's exclusive rights or to promote some overriding public interest.[5] The line between "abuse" and "public

---

[1] J. H. REICHMAN WITH CATHERINE HASENZAHL, NON-VOLUNTARY LICENSING OF PATENTED INVENTIONS, PART I—HISTORICAL PERSPECTIVE, LEGAL FRAMEWORK UNDER TRIPS AND AN OVERVIEW OF THE PRACTICE IN CANADA AND THE UNITED STATES (UNCTAD/ICTSD, September 2002) [hereinafter HISTORICAL PERSPECTIVE]; PART II—THE CANADIAN EXPERIENCE (UNCTAD/ICTSD, October 2002) [hereinafter THE CANADIAN EXPERIENCE]; PART III—THE LAW AND PRACTICE OF THE UNITED STATES (UNCTAD/ICTSD, forthcoming 2004) [hereinafter LAW AND PRACTICE OF THE UNITED STATES].

[2] 18 USC §§200, 201(f), 203(1)(a).

[3] [cites]

[4] See TRIPS Agreement, *supra* note 3, art. 31; REICHMAN WITH HASENZAHL, HISTORICAL PERSPECTIVE, *supra* note 1.

[5] See REICHMAN WITH HASENZAHL, LAW AND PRACTICE OF THE UNITED STATES, *supra* note 1 [cites at fn 497]

interest" is seldom sharply delineated, and in many instances statutory definitions of abuse invoke the public interest as an additional criterion for intervention. Typical grounds for triggering these compulsory licenses are the "need to ensure adequacy of supply" and "to regulate the availability of products deemed vital to security, *public health*, or environmental protection."[6]

The United States Congress has consistently declined to enact any general compulsory licensing provision of the kind adopted by other countries. In this country, compulsory licenses are available for antitrust violations and for government use of patents, while courts may decline to enforce patents in infringement actions under common-law doctrines of misuse. Beyond these limited circumstances, the availability of a nonvoluntary license for abuse or on public interest grounds in the United States depends primarily on specialized enabling statutes or on specialized clauses incorporated into specific statutes.[7]

The Bayh-Dole Act's requirement that patented products be made available "to the public on reasonable terms" is one of the clearest examples of such a specialized enabling clause. It may be compared with a Canadian statute that authorized compulsory licenses for acts of abuse, which occur, *inter alia,* "if the demand for the patented article in Canada is not being met to an adequate extent and on reasonable terms."[8]

The legislative history of the Bayh-Dole Act confirms that qualified experts viewed the relevant provisions as authorizing a compulsory license either for abuse or on public interest grounds.[9] For example, Harry. F. Manbeck, then General Patent Counsel for General Electric [and later a Commissioner of Patents] stated that "[I]f [a contractor] fails to supply the market adequately at a fair price, then there is reason for requiring it to license both the background patents and the patents stemming from the contract work."[10] U.S. Comptroller General Staats expressed DOE's views that "march-in rights *to protect the public's interest* were developed to take care of and address … [a] contractor's *windfall profits* … and detrimental effects to competition…"[11]

The reason for express legislative concerns about abuse and the public interest in the Bayh-Dole context are clear from the record. Under normal conditions, the patentee assumes the full risk of his or her research and development expenditures, and in U.S. law, there are relatively few constraints on the licensing practices by means of which the patentee tries to recoup that investment and turn a profit. Under Bayh-Dole, however, the government will have funded a significant part of the patentee's R&D costs and thus attenuated the risk. While there was a consensus that releasing the research product to

---

[6] [cites at fn 498].
[7] *Id*. [cite 503]
[8] See REICHMAN WITH HASENZAHL, THE CANADIAN EXPERIENCE, *supra* note 1, at 20-22 (discussing §65(2) of Canada's Patent Act of 1985).
[9] See generally Halperin, at ___.
[10] [cite Halperin, n. 21] (emphasis supplied).
[11] [cite id., n. 22]

private industry would augment applications and benefit economic growth generally, the march-in provisions were added to ensure that patentees' did not abuse their position by making the products available to the public on unreasonable terms that could lead to "windfall profits, [the] suppression of technology, and … detrimental effects to competition."[12]

A State's ability to impose compulsory licenses to regulate abuses of a foreign patentee's exclusive rights under domestic law has been regulated by article 5A of the Paris Convention for more than 75 years, and these provisions were incorporated into the TRIPS Agreement of 1994. The large body of state practice in implementing these norms over time was succinctly and authoritatively summarized by Bodenhausen in 1967, as follows:

> [W]hen national legislation is aiming at preventing *the abuses which might result from the exercise of the exclusive rights conferred by the patents*, the rules given in paragraphs (3) and (4) [of article 5A, Paris Convention] are mandatory for the member states…
>
> [E]xamples of such abuses may exist in cases where the owner of the patent, although working the patent in the country concerned, refuses to grant licenses on reasonable terms and thereby hampers industrial development, or does not supply the national market with sufficient quantities of the patented product, or *demands excessive prices, for such products.* The member states are free to define these, and other abuses.[13]

This international practice is consonant with the legislative history of the march-in right under Bayh-Dole, as appears, for example, from Harry Manbeck's reference to a contractor's failure "to supply the market adequately at a fair price," quoted above. In his and other's views, march-in rights were thus "part of the answer to the so-called windfall situation."[14]

Apart from the legislative history, which is consistent with international practice, it cannot logically be doubted that the language in the Bayh-Dole Act requiring patented products to be made available to the public on reasonable terms encompasses the patentee's pricing strategy. All unreasonable terms and conditions that rise to the level of actionable abuses have as their object the power, directly or indirectly, to increase the licensor's prices beyond the level that competition would otherwise ensure and thus to enhance profits. When patentees impose "field of use" or other licensing restrictions, when they engage in illegal tying, or as in the case at hand, they adopt a marketing

---

[12] Staat, Halperin n. 23; see generally Halperin; Arno & Davis.

[13] G. H. C. BODENHAUSEN, GUIDE TO THE APPLICATION OF THE PARIS CONVENTION FOR THE PROTECTION OF INDUSTRIAL PROPERTY AS REVISED AT STOCKHOLM IN 1967 70-71 (1968) (emphasis supplied).

[14] Cite at Halperin nn. 21, 23.

strategy consistent with the practice known as "monopoly leveraging,"[15] they are not conducting scientific or economic experiments for the sake of increasing academic knowledge. They pay their lawyers to devise contractual conditions that will enable them to raise prices and make more money.

In this connection, one should recall that individual members of the public do not typically negotiate with their pharmacies when they purchase medicine. They buy the product and pay the price that market conditions permit the pharmacist to charge. These conditions, in turn, result from the contracts stipulated between patent holders as licensors and their various licensees. When the Bayh-Dole Act affirms that the resulting products must be made available to the public on reasonable terms, it can only mean that the underlying licensing agreements should not undersupply the market, unduly distort competition, or otherwise leverage the procurement of active ingredients in ways that boost the price to unreasonable "windfall" levels that many users cannot afford.

While the Bayh-Dole march-in provisions thus clearly contemplate practices that produce excessive prices—what Manbeck and others called "windfall profits"—and would make no sense if they did not, I hasten to add that the Act in no way implies a regime of price controls, like that adopted in Canada and many EU countries. Indeed, loose assertions about "price controls" merely create confusion and divert attention away from the real issues bearing on the patentee's specific marketing strategies.

Statutes that seek to prevent abuses or otherwise to protect the public interest, like the march-in provisions of the Bayh-Dole Act, normally leave patentees free to adopt the marketing strategies they deem suitable. They do not require regulatory approval of prices, as would be the case under, say, Canada's regulatory agency, the Patented Medicines Prices Review Board (PMPRB).[16] By the same token, the marketing strategies that the patentee actually adopts, and their impact on the availability of the relevant products to the consumers on reasonable terms, is always open to public scrutiny and challenge on objective grounds of abuse. In the Bayh-Dole context, this would necessarily require attention to the taxpayers' interests as well as those of the patentee, including the ability of purchasers to afford critical, life-saving medicines and not be charged prices that "create … hardship for the overall public or for individual members of the public."[17]

In the case at hand, there is objective evidence that Abbott has imposed a 400% price increase in order to steer consumers away from competing products that would otherwise be made available to the public at much lower prices. There is further evidence that this strategy imposes hardship on patients that would particularly benefit from the lower priced products. At least one leading expert in the field believes that Abbott's strategy may turn out to violate prescriptions against one form of abuse known as monopoly

---

[15] Interview with Professor Arti Rai, Duke University School of Law.
[16] See REICHMAN WITH HASENZAHL, THE CANADIAN EXPERIENCE, *supra* note 1, at 43-44.
[17] Halperin, at 13.

leveraging.[18]

These are questions of fact and law that require investigation and due deliberation.[19] Although the practices under review appear questionable to me, it is not my task to anticipate the conclusions that the NIH may reach. I am here to testify that, under the march-in provisions of the Bayh-Dole Act as they were adopted, the NIH does have a solemn obligation to undertake this enquiry in good faith, with a view to determining whether the products of federally funded research are in fact being made available to the public under reasonable terms and conditions.

[18] Image Technical Services, Inc. V. Eastman Kodak Co., 125 F.3d 1195 (9th Cir. 1997).

[19] See, e.g., Arti K. Rai and Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 LAW & CONTEMP. PROBS. 289, 294 (2003).